RECEIVED AT DRUG SAFETY SURVEILLANCE
19-FEB-1998-0660

McNEIL

McNEIL CONSUMER PRODUC
FORT WASHINGTON, P

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Individual Safety Report
3031677-3-00

A. Patient information

1. Patient Identifier	2. Age at time of event:	3. Sex	4. Weight
Case 200 In confidence	75 yrs or Date of birth:	( )female (X)male	unk lbs or kgs

B. Adverse event or product problem

1. X Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

(X) death (mo/day/yr) unknown
( ) life-threatening
(X) hospitalization - initial or prolonged
( ) disability
( ) congenital anomaly
( ) required intervention to prevent permanent impairment/damage
( ) other:

3. Date of event (mo/day/yr): unknown

4. Date of this report (mo/day/yr): 02/09/98

5. Describe event or problem

Case # 200 received from the [redacted] 1996 case fatality data.
See attached case report form provided by [redacted]

FEB 1 1998

6. Relevant tests/laboratory data, including dates

See attached case report form provided by [redacted]

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

See attached case report form provided by [redacted]

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
#1 unknown acetaminophen product
#2

2. Dose, frequency & route used
#1 unknown dose, po
#2

3. Therapy dates (if unknown, give duration) from/to (or best estimate)
#1 previous 2-3 days
#2

4. Diagnosis for use (indication)
#1 "didn't feel well"
#2

5. Event abated after use stopped or dose reduced
#1 ( ) Yes ( ) No (X) N/A
#2 ( ) Yes ( ) No ( ) N/A

6. Lot # (if known)
#1 Unknown
#2

7. Exp. date (if known)
#1 Unknown
#2

8. Event reappeared after reintroduction
#1 ( ) Yes ( ) No (X) N/A
#2 ( ) Yes ( ) No ( ) N/A

9. NDC # - for product problems only (if known)
- -

10. Concomitant medical products and therapy dates (exclude treatment of event)
See attached case report form provided by [redacted]

G. All manufacturers

1. Contact office - name/address (& mfring site for devices)
McNeil Consumer Products Company
Medical Affairs
7050 Camp Hill Road
Ft. Washington, PA 19034

2. Phone number: 215-233-7820

3. Report source (check all that apply)
( ) foreign
( ) study
(X) literature
( ) consumer
(X) health professional
( ) user facility
( ) company representative
( ) distributor
( ) other:

4. Date received by manufacturer (mo/day/yr): 01/30/98

5.
(A) NDA # 17-552
IND #
PLA #
pre-1938 ( ) Yes
OTC product (X) Yes

6. If IND, protocol #

7. Type of report (check all that apply)
( ) 5-day (X) 15-day
( ) 10-day ( ) periodic
(X) initial ( ) follow-up #

8. Adverse event term(s)
OVERDOSE
STUPOR
LIVER FAILURE
KIDNEY FAILURE
COAGULATION DIS
DEATH

9. Mfr. report number: 0929699A

E. Initial reporter

1. Name, address & phone #
[redacted] MD
[redacted] Centers
Suite [redacted] Avenue
[redacted]

2. Health professional?	3. Occupation	4. Initial reporter also sent report to FDA
(X) Yes ( ) No	physician	( ) Yes ( ) No (X) Unk

FDA
Facsimile Form 3500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

[redacted] FATALITY: 1996 [redacted]

Case Number: 200

Age:	75 yrs
Substances:	Acetaminophen
Chronicity:	Chronic
Route:	Ingestion
Reason:	Ther error
Pre-Hospital Arrest?	No

A 75-year-old man with a history of alcoholism presented to the ED unresponsive. He had been taking an unknown amount of acetaminophen over the course of the previous 2-3 days because he didn't feel well. By the time the poison center was consulted, the patient was intubated and unresponsive with evidence of liver and renal failure. His laboratory studies revealed, ethanol, 50 mg/dL; acetaminophen, 32 mg/L; AST, 8000 U/L; creatinine, 4 mg/dL; BUN, 24 mg/dL; and an INR of 7.2. Therapy with N-acetylcysteine was recommended. The patient expired 19 hours after poison center consultation. It is unknown if the patient ever received NAC, and also unclear exactly how long the patient was in the hospital prior to death.